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2023

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Re: NOT-OD-23-091 *Request for Information in the NIH Plan to Enhance Public Access to the Results of NIH-Supported Research*

To Whom it May Concern:

The American Society of Hematology (ASH) appreciates the opportunity to provide comments on the *NIH Plan to Enhance Public Access to the Results of NIH-Supported Research* (NIH Public Access Plan) and the 2022 White House Office of Science and Technology Policy (OSTP) memo on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research.

ASH represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical hematological conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. As part of its mission to further the understanding, diagnosis, treatment, and prevention of disorders affecting the blood, ASH currently publishes two peer-reviewed journals, *Blood* and *Blood Advances*.

As a non-profit society publisher, ASH brings our best practices to the peer review of the articles and to wide dissemination of scholarly content in the field of hematology. The integrity of peer review is vital to sharing research findings in a way that assures accuracy, integrity, and the transmission of science that promotes new evidence vital to patient care. We are committed to public accessibility of scientific evidence as well as the need to preserve the US research enterprise as a source of high-quality scientific information. Our Society strongly recommends a two-year delay of the NIH Public Access Plan to adhere to the 2022 OSTP memo on Ensuring Free, Immediate, and Equitable Access to Federally Funded Research. This time would allow us to work with you to develop policies that sustain reliable, equitable, high quality scientific content.

ASH provides the following comments on NIH's Public Access Plan that focus on ensuring equity in publication opportunities for NIH-supported investigators, steps for improving equity in access and accessibility of publications, and early input on considerations to increase findability and transparency of research.

Ensuring equity in publication opportunities for NIH-supported investigators

Shifting of Revenue Streams

Opening papers prior to the current 12-month embargo will result in the loss of subscription revenue from institutions and individuals and, for many publishers, a corresponding decrease in advertising revenue. In order for publishers to provide the scientific community with the support it has become accustomed to, including, but not limited to, maintaining the integrity of the science, robust peer review, support for discoverability, reproducibility and dissemination of the science, the financial burden will shift to the authors. Diligent peer review, management and public disclosures of conflicts, and data and figure integrity checks are vital parts of a responsible publication process. Threats to the integrity of the content, such as plagiarism, paper mills, inappropriate AI generated content, and fraudulent data, are always present and require steady attention. While no system is perfect, peer-review increases the opportunity to mitigate these risks and protect the public from ensuing harms. Publishers also provide additional benefits to their communities by providing educational material, alternative metrics and enhanced metadata that may also suffer due to diminishing revenue. All of this requires resources that are likely to be endangered if publishers lose the revenue that currently sustains this work. Such losses could occur in the form of cancelled subscriptions, insufficient total article processing charge (APC) income, and lost licensing fees for approved reuse of content, among others.

Policies that restrict publishers' abilities to collaborate with authors to realize their protection of rights under United States copyright law would further limit revenue streams on which we depend, including royalties, licensing, reprints, and advertising. We urge the NIH not to include rights retention language or license requirements in the final policy other than the grantee's right to deposit the manuscript. Preserving a Green OA route presents a sustainable business model that should be embraced. Expanding rights retention policies beyond the deposition of the manuscript would also erode the publisher's ability to monitor usage of the content in support of the author's intellectual property.

Access to funding

OSTP and NIH state that grants can be used to cover publication costs, which is a positive step; however, it is important that NIH increase the total amount of grant funding per award so that the additional Article Processing Charges, including potential fees to deposit papers into PubMed Central for example, will not reduce the funds available for research.

In addition, we are concerned that certain grants do not permit use of funds for publication fees. As such, ASH recommends that NIH exempt certain types of infrastructure-related grants (e.g., cancer center support grants, CTSA's, NCORPs) and teaching grants (K awards, T awards) from reporting funding to journals and thus requiring deposit.

The broad reach and impact of this proposed plan will be a challenge to implement and enforce if compliance is mandated for all NIH funded investigators regardless of how much funding they received or how small a role any given individual plays in a research project or manuscript. The NIH should instead apply a minimum threshold of funding and/or level of participation by authors and researchers before subjecting papers to the proposed mandate.

Copyright protection

Copyright protection is the first line of defense for any author against the misuse of their research, and publishers stand ready to defend investigators' intellectual property. Journals customarily allow authors to post their paper on their institutions' site, make use of their work at conferences, but this

policy needs to clearly state that making the content freely accessible does not give anyone the right to create derivative products without permission. Clarification that the rights remain with the copyright holder needs to be articulated. The final guidance should also clarify that authors are obligated to follow the NIH Guidelines only for the papers they author as a result of NIH funding.

Definition of First Publication

There is confusion in the community concerning the definition of First Publication. The Society is interpreting NIH's draft language regarding first publication to mean that the manuscript uploaded to PubMed Central in compliance with this policy will be embargoed until the first appearance of the final typeset article. Are we also correct in understanding that the Pub Med Central first publication will include a link to the publisher's site? Clarification of this matter in the final policy is strongly recommended to avoid confusion in the community.

Steps for improving equity in access and accessibility of publications

Access and accessibility of publications

Journal publishers have long been collaborating with various stakeholders to develop and implement collaborative projects that enhance the public access, utility, preservation, and discoverability of materials that report on and analyze and interpret results of federally funded research. Publishers participate in a multitude of services that enhance discoverability, including ORCID, Crossref, the Committee on Publication Ethics, and provide guidelines that are not influenced by pharmaceutical companies as well as making sure conflicts of interest are accurately noted. Federal agencies should collaborate with publishers and other stakeholders to ensure minimum standards, share best practices, and minimize duplication of work.

Providing immediate access to all scientific research comes with significant issues and significant financial/labor costs of compliance. ASH wants to make sure that authors' intellectual property remains accurately presented on the worldwide stage; we are concerned that the research could be pirated by outside bodies that may misinterpret the results to suit their needs. While publisher's efforts to support free, immediate access to COVID-19 research were a boon to scientists, we also saw a rise of misuse and misunderstanding of research among the public. Strong intellectual property protections are a necessary safeguard against the acceleration of this trend. We recommend that NIH support publisher's ability to enforce copyright protection by maintaining publishers' rights in and to the content published.

Early input on considerations to increase findability and transparency of research

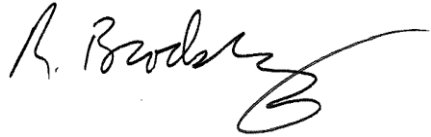
Consistent Guidance

There are many examples of advancements already accepted by the industry such as DOIs, ORCID, funder registries, discovery tools for content mining, and use of JATS for structured metadata to increase findability and transparency of research. If NIH wants to aggregate these data, ASH recommends collaboration with various stakeholders to create and engage in guidance for authors and publishers regarding standards to ensure best practices and minimize duplication of work.

Thank you for the opportunity to provide our thoughts regarding NIH's Public Access Plan. Please contact Suzanne Leous, MPA, Chief Policy Officer (sleous@hematology.org) or Nina Hoffman, Chief

Publications Officer (nhoffman@hematology.org), should you have any questions regarding ASH's comments.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Brodsky", with a stylized flourish at the end.

Robert A. Brodsky, MD
President